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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/685,828	10/10/2000	Elliott S. Klein	17171CIP4DIV	4591

7590 07/16/2002
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EXAMINER

HILL, MYRON G

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 07/16/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/685,828

Applicant(s)

KLEIN ET AL.

Examiner

Myron G. Hill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21- 43 is/are pending in the application.
- 4a) Of the above claim(s) 26- 32, 34- 38, and 40- 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21- 25, 33, 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Applicant elected Group I with the species retinoid receptor as the elected species. Claims 26- 32, 34- 38, 40, and 41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6. It is noted that Applicant identified claim 35 as reading on the species. This claim is drawn to a steroid receptor and will not be examined unless further species are examined.

Claims under examination are 21- 25, 33, and 39 with the elected species of retinoid receptor.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21- 25, 33, and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear if the agonist in claim 21 a) line 1 is the ligand recited in b) line 4. The method of claim 21 is not clear. Is the first part of part "b" a recap of part "a"? There is a comparison part "b" in the claim; however, since all unknown compounds are not going to be inverse agonists, it is not clear what

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result of the comparison is needed to determine and conclude that the compound is a inverse agonist. In other words, it is not clear if the method results in the determining whether a compound is an inverse agonist as a conclusion and what result indicates that determination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 21- 25, 33, and 39 are rejected under 35 U.S.C. 102(a) as being anticipated by Klein (1996 J Bio Chem from IDS).

Klein teaches a method of determining inverse agonists as claimed. Klein teaches a method to determine reverse agonists with two peptides, one being a peptide with a ligand binding region and a ligand dependant activating region and a second peptide having a promoter sensitive to stimulation by the ligand dependent activation region of the first peptide the expresses a luciferase gene (abstract and Figure 2).

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application

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being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 21- 25, 33, and 39 are rejected under 35 U.S.C. 103(a) as being obvious over Klein (US 5776699).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(I)(1) and § 706.02(I)(2).

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Klein '699 discloses the claimed invention. Claim 1, 3-5, and 14- 20 as well as Columns 17- 20 and Examples 10, 11, and 12 teach a method of identifying a compound with the properties of an inverse agonist (Column 10, lines 48- 51 equates the term inverse agonist with negative hormone) retinoid receptors using polypeptides, one comprises retinoid receptor ligand binding domain, and ligand dependent transactivating domain, and a second polypeptide comprises a reporter gene the expression of which is sensitive to stimulation by transactivation by first peptide. Klein teaches luciferase reporter gene and cells transfected with plasmids. One of ordinary skill in the art at the time of the invention would have also known that DNA of interest could be integrated into chromosome of host cell as well.

Double Patenting

Claims 21- 25, 33, and 39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3- 5, and 14- 20 of U.S. Patent No. 5776699. Although the conflicting claims are not identical, they are not patentably distinct from each other because Klein recites a method of identifying a compound with the properties of an inverse agonist (Column 10, lines 48- 51 equates the term inverse agonist with negative hormone) retinoid receptors using polypeptides, one comprises retinoid receptor ligand binding domain, and ligand dependent transactivating domain, and a second polypeptide comprises a reporter gene the expression of which is sensitive to stimulation by transactivation by first peptide. Klein

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teaches luciferase reporter gene and cells transfected with plasmids. One of ordinary skill in the art at the time of the invention would have also known that DNA of interest could be integrated into chromosome of host cell as well as carried by plasmids.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Myron G. Hill
Patent Examiner
July 14, 2002

Mary Mosher
**MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800**